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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,321	04/14/2005	Hiroyuki Ebinuma	270475US0PCT	7005

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
07/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/531,321	Applicant(s) EBINUMA, HIROYUKI	
	Examiner Qiuwen Mi	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to..See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/14/05, 7/07/05, 6/16/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment in the reply filed on 6/11/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Claims Pending

Claims 1-8 are cancelled. Claims 9-30 are newly submitted. Claims 9-30 are pending. Claims 9-30 are examined on the merits.

Claim Rejection 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of removing a fructosyl group from a fructosylated peptide or protein comprising reacting the fructosylated peptide or protein with an isolated enzyme from plant that removes a fructosyl group from a fructosylated peptide or a fructosylated

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protein. The claims are also drawn to an isolated enzyme removes a fructosyl group from a fructosylated peptide or a fructosylated protein.

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the invention only provides the description of a method of removing a fructosylated peptide a fructosylated protein using a crude aqueous extract from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc (plant species that have shown data in examples and drawings). Applicant does not have the possession of a method of removing a fructosylated peptide a fructosylated protein using isolated enzyme from the whole family Rosaceae, Vitaceae, and Umbelliferae or the whole plant kingdom; or an isolated enzyme that removes a fructosylated peptide a fructosylated protein from the family Rosaceae, Vitaceae, and Umbelliferae or the whole plant kingdom. Accordingly, in the absence of sufficient recitation of the compound with the corresponding structure and functional activity, the specification does not provide adequate written description of the claimed invention.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 9-30 are broad generics, with respect to all possible plants from the Rosaceae, Vitaceae, and Umbelliferae or the whole plant kingdom. Wikipedia Online indicates that the Rosaceae or rose family is a large

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family of plants, with about 3,000-4,000 species in 100-120 genera; Vitaceae comprises 12 genera and more than 700 species; Umbelliferae comprises 300 genera and more than 3,000 species; and there are totally 350,000 species of plants. The specification lacks sufficient variety of species reflect the large variance within the family Rosaceae, Vitaceae, Umbelliferae or the whole plant kingdom.

It is well known in the art that multitudes of proteins and natural compounds have been isolated from a crude aqueous extract of a plant, and each crude aqueous extract obtained from a plant is unpredictable in nature. A crude aqueous extract of a plant is very different from an isolated enzyme, as the latter requires the isolate a particular enzyme from one extract of a crude aqueous extract of a plant, purification, identification of a sequence of an enzyme, and co-relate each enzyme with claimed functional activity. It is the opinion of the Examiner that the specification does not provide adequate written description of any isolated enzyme that removes a fructosylated peptide a fructosylated protein. What Applicant is in possession is a method of removing a fructosylated peptide a fructosylated protein using a crude aqueous extract from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc (plant species that have shown data in examples and drawings).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed. The specification does not “clearly allow persons of ordinary skill in

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the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed compound being claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the compound. Adequate written description requires more than a mere statement of the total amount of the plant material being used. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

Claims 9-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of removing a fructosylated peptide a fructosylated protein using a crude aqueous extract from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc, does not reasonably provide enablement for a method of removing a fructosylated peptide a fructosylated protein using isolated enzyme from the whole family Rosaceae, Vitaceae, and

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Umbelliferae or the whole plant kingdom; or an isolated enzyme that removes a fructosylated peptide a fructosylated protein from *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc , or the family Rosaceae, Vitaceae, and Umbelliferae or the whole plant kingdom. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As mentioned above, the invention only provides the description of a method of removing a fructosylated peptide a fructosylated protein using a crude aqueous extract from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc (plant species that have shown data in examples and drawings), and no description regarding the isolation procedure of any particular enzyme is being disclosed in the specification. It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to isolate a particular enzyme from one extract of a crude aqueous extract of a plant, purification, identification of a sequence of an enzyme, and correlate each enzyme with claimed functional activity, that Applicant is not enabled for any isolated enzyme, a method of removing a fructosylated peptide a fructosylated protein using an isolated enzyme from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc, let alone a method of removing a fructosylated peptide a fructosylated protein using an isolated enzyme from the family Rosaceae, Vitaceae, and Umbelliferae, or an isolated enzyme from the whole plant kingdom, as instantly claimed. Considering this evidence, the skilled artisan, lacking information with regard to any isolated enzyme which will lead to the instantly claimed invention, would necessarily need to perform tedious trial and error protocols without

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expectation of success in order to ascertain what isolated enzyme would provide for the specific defructosylation as described in the specification.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue

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experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims. What Applicant does enable is a method of removing a fructosylated peptide a fructosylated protein using a crude aqueous extract from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc (plant species that have shown data in examples and drawings).

Applicant is advised to claim a method of removing a fructosylated peptide a fructosylated protein using a crude aqueous extract from plants *Pyrus pyrifolia*, *Vitis vinifera*, or *Daucus carota* etc (plant species that have shown data in examples and drawings) through product by process claims.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 10-15, and 27 are vague and indefinite. For instance, claim 9 recites “an isolated enzyme obtainable from...”; claim 10-15 state “said enzyme may be obtained from”; claim 27 recites “an isolated enzyme having the ability to...” . The phrase "obtainable", “may be”, or “having the ability” renders the claim indefinite because it is unclear whether the

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limitations are part of the claimed invention. See MPEP § 2173.05(d). Applicant is suggested to use “obtained”, or “is” instead.

Although claims 16-26, and 28-30 are not specifically recited for containing indefinite matter, because these claims are dependant upon claims 9, 10-15 and 27, claims 16-26, and 28-30 necessarily comprise all of the limitations of 9, 10-15 and 27. Because claims 16-26, and 28-30 do not remedy the indefiniteness of claims 9, 10-15 and 27 these claims are also properly rejected under this statute.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27 and 29 are rejected under 35 USC § 102 (b) as being anticipated by Thumm (US 4,976,974).

Thumm teaches grape juice from the crushing followed by centrifugation (col 3, lines 25-30).

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Therefore, the reference is deemed to anticipate the instant claim above.

Claims 27 and 28 are rejected under 35 USC § 102 (b) as being anticipated by JP 60109509.

JP 60109509 teaches a water extract of *Prunus persica* (see Abstract)

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 27 and 30 are rejected under 35 USC § 102 (e) as being anticipated by Biyani et al (US 6,361,818).

Biyani et al teach obtaining clear liquid extract of *Daucus carota* by crushing, filtering, and centrifugation (col 5, Example).

Therefore, the reference is deemed to anticipate the instant claim above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/

Patricia Leith

Primary Examiner

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